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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,515	05/01/2002	Dan L. Eaton	10466/300	8122

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/063,515	EATON ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1204*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 12/10/2004 has been entered. Claims 1-5 are pending and being examined.

Inventorship

In view of the papers filed 12/10/2004, the inventorship in this nonprovisional application has been changed by the deletion of Dan L. Eaton, Ellen Filvaroff, Mary E. Gerritsen, and Colin K. Watanabe.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC §§ 101, 112

Claims 1-5 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Applicants argue that utility need not be proved to an absolute certainty and that a correlation between the evidence and the asserted utility is sufficient; that the accepted understanding in the art is that there is a correlation between gene expression and the level of the encoded protein; that it is Applicants' position that a change in gene expression establishes a significant probability that the encoded polypeptide will also be changed; that the legal standard for demonstrating utility is more likely than not, and that the standard is not absolute certainty;

and, that it is more likely than not that those skilled in the art would believe that the PRO874 polypeptide and antibodies thereto are useful as a diagnostic tool for cancer.

Applicant's arguments have been fully considered but they are not persuasive.

The present rejection is not based upon "an absolute certainty," "absolute predictability," or "an invariable exact correlation." The present rejection is based upon Applicants' failure to disclose to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. The M.P.E.P. reminds Office personnel that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. The examiner has cited countervailing evidence to show that the skilled artisan would have a legitimate basis to doubt the utility of the PRO874 polypeptide because the skilled artisan recognizes that protein levels are not always consistent with mRNA levels. This evidence provides a reason for one skilled in the art to question the objective truth of the statement of diagnostic or therapeutic use of the claimed antibodies. In the absence of any information on the role, activity, or expression of the PRO874 polypeptide in cancer, the examiner therefore considers these asserted utilities to not be specific and substantial because the skilled artisan would not know if PRO874 polypeptide expression could, would or should be upregulated, down-regulated, or unchanged in cancer.

As noted by Applicants, "testing is often required to establish practical utility." In the present case, the specification does not provide any testing of the level of expression, activity, or role in cancer of the PRO874 polypeptide. In the absence of this testing and in the presence of

evidence that protein levels are not always consistent with mRNA levels, there is no basis for concluding that the skilled artisan would be convinced that there is a "reasonable probability" that the PRO874 polypeptide could be used for the diagnosis or treatment of cancer. In contrast to situations where in vitro testing of a novel pharmaceutical compound was sufficient to establish practical utility, the present specification does not provide any testing of the level of expression, activity, or role in cancer of the PRO874 polypeptide.

Applicants argue that they have established that the gene encoding the PRO874 polypeptide is underexpressed in lung tumors and is useful as a diagnostic tool, and therefore the corresponding polypeptide and antibodies are useful as diagnostic tools, as evidenced by the Grimaldi declaration (Exhibit 1). Applicant's arguments have been fully considered but they are not persuasive. The declaration of J. Christopher Grimaldi under 37 CFR 1.132 filed 12/10/2004 (Exhibit 1) is insufficient to overcome the rejection of claims 1-5 based upon a lack of utility as set forth in the last Office action because: Declarant argues that it was determined whether the polynucleotides tested were more highly expressed, less expressed, or whether expression remained the same and that the results of these gene expression studies can be used to differentiate tumor from normal. Declarant argues that if a difference is detected, this indicates that the gene and its corresponding polypeptide and antibodies against the polypeptide are useful for diagnostic purposes. Declarant's arguments have been fully considered but they are not persuasive. All polynucleotides/polypeptides from a particular tumor sample can invariably be classified as either more highly expressed, less expressed, or unchanged expression as compared to some standard level of expression. It can then be asserted that any protein/polynucleotide that is expressed in this manner can be used to detect or characterize the tumor. Such utilities are

analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility. Furthermore, no information is provided in the differential tissue expression distribution data regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide. The present rejection is based upon Applicants' failure to disclose to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. The examiner has cited countervailing evidence to show that the skilled artisan would have a legitimate basis to doubt the utility of the PRO874 polypeptide. The skilled artisan would not know if PRO874 polypeptide expression could, would or should be upregulated, down-regulated, or unchanged in cancer. Therefore, the disclosure that DNA40621-1440 is more highly expressed in normal lung as compared to lung tumor does not impute a specific, substantial, and credible utility to the claimed antibodies that bind the PRO874 polypeptide. Based on the present disclosure, one skilled in the art would be required to carry out further research to identify or reasonably confirm a "real world" context of use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Applicants argue that they have established that the accepted understanding in the art that there is a reasonable correlation between gene expression and expression of the encoded protein, that there does not need to be necessary connection between gene expression and protein expression, but that there only need to be a reasonable correlation, and that data indicating that a gene is over- or under-expressed in cancer is persuasive evidence that the encoded protein is over- or under-expressed in cancer, as evidenced by the declarations of Grimaldi (Exhibit 2) and

Polakis (Exhibit 3), and the teachings in the Molecular Biology of the Cell (Exhibit 4). Applicants acknowledge that there is no necessary correlation between gene expression levels and protein expression levels, but that a necessary correlation is not required to establish an asserted utility because there need only be a reasonable correlation. Applicant's arguments have been fully considered but they are not persuasive. The declaration of J. Christopher Grimaldi under 37 CFR 1.132 filed 12/10/2004 (Exhibit 2) is insufficient to overcome the rejection of claims 1-5 based upon a lack of utility as set forth in the last Office action because: Declarant argues that comparison of gene expression levels in normal versus diseased tissue has important implications, that two cell samples that have differing mRNA concentrations for a specific gene are expected to have correspondingly different concentrations of protein for that gene, that if the dogma that a change in mRNA will represent a similar change in protein did not hold true then techniques used to detect mRNA would have little value and not be so widely used, and that the detection of increased or decreased polypeptide expression can be used for cancer diagnosis and treatment. Declarant's arguments have been fully considered but they are not persuasive. All polypeptides from a particular tumor sample can invariably be classified as either more highly expressed, less expressed, or unchanged expression as compared to a some standard level of expression. It can then be asserted that any protein that is expressed in this manner can be used to detect or characterize the tumor. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility. Furthermore, no information is provided in the differential tissue expression distribution data regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide. The present rejection is based upon Applicants' failure to disclose to disclose enough

information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. The examiner has cited countervailing evidence to show that the skilled artisan would have a legitimate basis to doubt the utility of the PRO874 polypeptide. The skilled artisan would not know if PRO874 polypeptide expression could, would or should be upregulated, down-regulated, or unchanged in cancer. Therefore, the disclosure that DNA40621-1440 is more highly expressed in normal lung as compared to lung tumor does not impute a specific, substantial, and credible utility to the claimed antibodies that bind the PRO874 polypeptide. Based on the present disclosure, one skilled in the art would be required to carry out further research to identify or reasonably confirm a "real world" context of use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. The examiner can accept, for arguments sake, that gene expression analysis, tools or techniques have the potential for the discovery of new diagnostic or therapeutic targets. However, in the present case no information is provided in the differential tissue expression distribution data regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide. The examiner does not agree that such a disclosure provides a "specific benefit in currently available form." This further characterization is part of the act of invention and until it has been undertaken, Applicants' invention is incomplete. Unlike the situation in Grimaldi (Blood. 1989 Jun;73(8):2081-5), wherein chromosomal translocations have proven to be important markers of the genetic abnormalities central to the pathogenesis of cancer, there is no evidence that the present situation involves the cloning of a chromosomal breakpoint. Unlike the situation in Meeker (Blood. 1990 Jul 15;76(2):285-9), wherein serum IL-3 levels were measured and shown to correlate with

disease activity, in the present case the specification does not provide any testing of the level of expression, activity, or role in cancer of the PRO874 polypeptide. Unlike the situation in Singleton (Pathol Annu. 1992;27 Pt 1:165-90), in the present case the specification does not provide any testing of the level of expression, activity, or role in cancer of the PRO874 polypeptide.

Declarant argues that even in cases where protein and mRNA expression do not correlate, this still provides significant information useful for cancer diagnosis and treatment because it enables more accurate tumor classification and hence better determination of a suitable therapy. Declarant's arguments have been fully considered but they are not persuasive. In effect, Declarant's position is that the claimed antibodies that bind the PRO874 polypeptide are useful because those of skill in the art could experiment and figure out for themselves what any observed experimental results might mean. The examiner does not agree that such a disclosure provides a "specific benefit in currently available form." This further characterization is part of the act of invention and until it has been undertaken, Applicants' invention is incomplete.

The declaration of Paul Polakis under 37 CFR 1.132 filed 12/10/2004 (Exhibit 3) is insufficient to overcome the rejection of claims 1-5 based upon a lack of utility as set forth in the last Office action because:

Declarant states that the primary focus of the Tumor Antigen Project was to identify tumor cell markers useful as targets for cancer diagnostics and therapeutics. Dr. Polakis states that approximately 200 gene transcripts were identified that are present in human tumor cells at significantly higher levels than in corresponding normal human cells. Declarant states that antibodies to approximately 30 of the tumor antigen proteins have been developed and used to

show that approximately 80% of the samples show correlation between increased mRNA levels and changes in protein levels. Declarant states that an increased level of mRNA in a tumor cell relative to normal cell typically correlates to a similar increase in the encoded protein. Declarant states that it remains a central dogma in molecular biology that increased mRNA levels are predictive of corresponding increased levels of the encoded protein. Dr. Polakis characterizes the reports of instances where such a correlation does not exist as exceptions to the rule. Declarant's arguments have been fully considered but they are not persuasive. The present application provides no information regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide. Only mRNA expression data was presented. The present rejection is based upon Applicants' failure to disclose to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. The examiner has cited countervailing evidence to show that the skilled artisan would have a legitimate basis to doubt the utility of the PRO874 polypeptide. The skilled artisan would not know if PRO874 polypeptide expression could, would or should be upregulated, down-regulated, or unchanged in cancer. Furthermore, a "dogma" is an authoritative principle, belief, or statement of ideas or opinion, especially one considered to be absolutely true. Allman provides evidence that Polakis's asserted dogma is not absolutely true and that the skilled artisan would have a legitimate basis to doubt the utility of antibodies that bind the PRO874 polypeptide based solely on the disclosure regarding DNA40621-1440 in Example 18 on page 141 of the present specification.

Applicants further argue that Allman supports Applicants position that it is well established that in general, the level of protein is positively correlated to the level of mRNA

because Allman's findings were unexpected. Applicant's arguments have been fully considered but they are not persuasive. Allman supports the examiner's position that Applicants' have failed to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention and that the skilled artisan would have a legitimate basis to doubt the utility of antibodies that bind the PRO874 polypeptide.

The teachings in the Molecular Biology of the Cell (Exhibit 4) are acknowledged. However, in the present case the specification does not provide any testing of the level of expression, activity, or role in cancer of the PRO874 polypeptide. The skilled artisan would not know if PRO874 polypeptide expression could, would or should be upregulated, down-regulated, or unchanged in cancer.

Applicants argue that the claimed antibodies that bind the PRO874 polypeptide would have diagnostic utility even if there is no direct correlation between gene expression and protein expression because the identification of both gene expression and protein expression enables more accurate tumor classification and better determination of therapy, as evidenced by the paragraph 6 of the Grimaldi declaration (Exhibit 2), as echoed by the Ashkenazi declaration (Exhibit 6), and as further supported by Hanna (Exhibit 7).

Applicant's arguments have been fully considered but they are not persuasive.

Paragraph 6 of the declaration of J. Christopher Grimaldi under 37 CFR 1.132 filed 12/10/2004 (Exhibit 2) is insufficient to overcome the rejection of claims 1-5 based upon a lack of utility as set forth in the last Office action because: Declarant argues that even in cases where protein and mRNA expression do not correlate, this still provides significant information useful

for cancer diagnosis and treatment because it enables more accurate tumor classification and hence better determination of a suitable therapy. Declarant's arguments have been fully considered but they are not persuasive. In effect, Declarant's position is that the claimed antibodies that bind the PRO874 polypeptide are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. The examiner does not agree that such a disclosure provides a "specific benefit in currently available form." This further characterization is part of the act of invention and until it has been undertaken, Applicants' invention is incomplete.

The declaration of Dr. Ashkenazi under 37 CFR 1.132 filed 12/10/2004 (Exhibit 6) is insufficient to overcome the rejection of claims 1-5 based upon a lack of scope of enablement as set forth in the last Office action because:

Declarant asserts that amplification of certain genes gives cancer cells an advantage relative to normal cells. Declarant asserts that if the mRNA and gene product are over-expressed, then the gene product is a promising candidate for therapy. Declarant's arguments have been fully considered but they are not persuasive. The present claims are directed to or encompass antibodies that bind the PRO874 polypeptide (SEQ ID NO: 10). The present specification discloses:

> The PRO polypeptides and nucleic acid molecules of the present invention may also be used diagnostically for tissue typing, wherein the PRO polypeptides of the present invention may be differentially expressed in one tissue a: compared to another, preferably in a diseased tissue as compared to a normal tissue of the same tissue type. PRO nucleic acid molecules will find use for generating probes for PCR, Northern analysis, Southern analysis and Western analysis. Page 93, paragraph 0336.

> Identification of the differential expression of the PRO polypeptide-encoding nucleic acid in one or more tumor tissues as compared to one or more normal tissues of the same tissue type renders the molecule useful diagnostically for the determination of the

presence or absence of tumor in a subject suspected of possessing a tumor as well as therapeutically as a target for the treatment of a tumor in a subject possessing such a tumor. Page 140, paragraph 0530.

DNA40621-1440 is more highly expressed in normal lung than as compared to lung tumor. Example 18, Page 141.

However, no information is provided in the differential expression of the PRO polypeptide-encoding nucleic acid data regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide.

Declarant asserts that a gene protein product of an amplified gene is useful regardless of the expression level of the protein because parallel monitoring of gene amplification and protein expression provides better tumor diagnosis, treatment, or classification. Declarant's arguments have been fully considered but they are not persuasive. As discussed above, no information is provided in the differential expression of the PRO polypeptide-encoding nucleic acid data regarding the level of expression, activity, or role in cancer of the PRO874 polypeptide. The specification fails to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention. Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. The examiner accepts for argument's sake that a person skilled in the art could derive some data regarding PRO874 polypeptide expression in tumors in which PRO874 mRNA is differentially expressed. The examiner can also accept, for argument's sake, that such data could be used to correlate PRO874 polypeptide expression with PRO874 polynucleotide amplification or PRO874 mRNA differential expression. The skilled artisan might also be able to derive a practical way of using this data. This further

characterization, however, is part of the act of invention and until it has been undertaken, Applicants' invention is incomplete. In effect, Applicants' position is that the claimed antibodies that bind the PRO874 polypeptide are useful because those of skill in the art could experiment with them and figure out for themselves what any observed experimental results might mean. The examiner does not agree that such a disclosure provides a "specific benefit in currently available form."

It is acknowledged that, in general, FISH and HIC results with HER-2/neu correlate well (Hanna, Exhibit 7). However, discordant results are seen and the significance of these results is unclear (Hanna, first page, right column, last paragraph). Hanna states that HER-2/neu testing will utilize IHC as a screen, followed by FISH in IHC-negative cases (first page, right column, last paragraph), presumably to better understand the significance of these discordant results. This teaching does not provide a specific benefit in currently available form for the presently claimed antibodies that bind the PRO874 polypeptide. Therefore, in view of the evidnece that protien levels are not always consitent with protien levles, Hanna supports the examiner's position that the differential expression data of DNA40621-1440 does not impute a specific, substantial, and credible utility to the PRO874 polypeptide.

Applicants argue that the evidence of differential expression of the PRO874 polynucleotide, along with the declarations, provide a specific utility for the claimed antibodies that bind the PRO874 polypeptide. Applicant's arguments have been fully considered but they are not persuasive. Applicants' have failed to disclose enough information about the invention to make its usefulness immediately apparent to those familiar with the technological field of the invention and that the skilled artisan would have a legitimate basis to doubt the utility of the

PRO874 polypeptide. Thus, the DNA40621-1440 expression data does not impute a specific and substantial utility to the claimed antibodies.

Claims 1-5 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue that they have established a substantial, specific, and credible utility for the claimed antibodies that bind the PRO874 polypeptide. Applicant's arguments have been fully considered but they are not persuasive. As Applicants recognize, a rejection under § 112, first paragraph, may be maintained on the same basis as a lack of utility rejection under § 101. A deficiency under 35 U.S.C. 101 also creates a deficiency under 35 U.S.C. 112, first paragraph. If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112. Obviously, if a claimed invention does not have utility, the specification cannot enable one to use it. As such, a rejection properly imposed under 35 U.S.C. 101 should be accompanied with a rejection under 35 U.S.C. 112, first paragraph. The 35 U.S.C. 112, first paragraph, rejection set out a separate rejection that incorporates by reference the factual basis and conclusions set forth in the 35 U.S.C. 101 rejection. A 35 U.S.C. 112, first paragraph, rejection should be imposed or maintained when an appropriate basis exists for imposing a rejection under 35 U.S.C. 101.

New Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Support for the limitation "amino acids 34-321 of SEQ ID NO: 10" cannot be found in the disclosure as originally filed, which raises the issue of new matter. Applicants argue that support for this limitation can be found in paragraph 0196. Applicant's arguments have been fully considered but they are not persuasive. Paragraph 0196 discloses that it is conceivable and possible that other methionine residues located either upstream or downstream from the amino acid position 1 in the figures may be employed as the starting amino acid residue for the PRO polypeptides. However, the species methionine residue #34 as the starting amino acid is not supported by this generic disclosure because there is no express, implicit, or inherent support for this species to the exclusion of all the other species. In other words, there is no evidence of record that the disclosure would not reasonably lead the skilled artisan to this particular species.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, BRENDA BRUMBACK, CAN BE REACHED ON (571) 272-0961.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MARCH 25, 2005